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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,670	02/09/2004	Ramez Emile Necola Shehada	064693-0097	1453

7590 07/19/2006

MCDERMOTT, WILL & EMERY
Suite 3400
2049 Century Park East
Los Angeles, CA 90067

EXAMINER

GIBSON, KESHIA L

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,670

Applicant(s)NECOLA SHEHADA, RAMEZ
EMILE**Examiner**

Keshia Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 12-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/21/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/06 has been entered.

Response to Arguments

2. Applicant's arguments filed 6/21/06 have been fully considered but they are not persuasive.

3. In response to applicant's argument that Polanyl does not disclose an optical fiber distal end that branches away from the catheter. First, applicant is arguing limitations not found in the claim. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claim states that "the distal end branches away from the conduit's outer surface," not from the catheter. Second, although the claim does requires that the distal end of the optical fiber branch from the conduit's outer surface, the claim makes no distinction as to whether the distal end is located internally or externally of the catheter. As can be seen from the figures of Polanyl, the distal end of the fiber branches away from the conduit's outer surface.

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4. As for the recitation "for insertion in the tissue inside the patient's body," catheters are designed to be enter the body through an opening or passageway, generally artificial in nature, located within the tissue of the body. Polanyl further discloses that the catheter is to be inserted into the body and held in place (column 1, lines 1-59, column 2, lines 54-63). As such, Polanyl is considered to disclose that the catheter (and therefore the distal end of the optical fiber located therein) is configured for insertion in the tissue inside the patient's body.

5. In response to applicant's argument that "it is unclear why one of ordinary skill in the art would be motivated to combine the drain holes of Russo with Johnson and Polanyl to drain fluid from a body cavity since the examiner asserts that Johnson already performs the function of draining fluid from the body," again, such motivation was presented in the previous grounds of rejection. Additionally, it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted). Moreover, it is actually well known to provide surgical drains with drain holes; examiner presented motivation statements in view of Russo et al. to show a distinct teaching of such motivation.

6. Thus, despite applicant's arguments, Johnson in view of Polanyl, and in further view of Russo, is still considered to anticipate and/or render obvious the structural limitations set forth in Claims 1-9 and 12-14 of the claimed invention, as presented in

the previous Office Action (which has been modified and presented again, in view of applicant's amendments, below).

Claim Objections

7. Claims 12-14 are objected to because of the following informalities: it is suggested that the recitation "first optical fiber" in Claim 12 be changed to "second optical fiber" for the following reasons:

- a. Claim 1 references the first optical fiber as the fiber that branches away from conduit's outer surface. Claims 13-14 require that first optical fiber comprise a sensor embedded in the conduit. Looking for Figs. 4A and 4B, Fig. 4A appears to be the only embodiment having a branched optical fiber and an optical fiber with a sensor embedded within the conduit. However, as seen from the Figures, there is not an embodiment having an optical fiber that both branches from the conduit's outer surface AND comprises a sensor that is embedded in the conduit.
- b. As such, it appears that applicant intended for the claim to reference the "second optical fiber" and not the "first optical fiber"; an embodiment that would be supported by Fig. 4A. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. Claims 12-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an optical fiber that branches away from the conduit's outer surface and an optical fiber including a sensor embedded within the

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conduit, does not reasonably provide enablement for such limitations being provided by the same optical fiber. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Claim 1 references the first optical fiber as the fiber that branches away from conduit's outer surface. Claims 13-14 require that first optical fiber comprise a sensor embedded in the conduit. Looking for Figs. 4A and 4B, Fig. 4A appears to be the only embodiment having a branched optical fiber and an optical fiber with a sensor embedded within the conduit. However, as seen from the Figures, there is not an embodiment having an optical fiber that both branches from the conduit's outer surface AND comprises a sensor that is embedded in the conduit. As such, it appears that applicant intended for the claim to reference the "second optical fiber" and not the "first optical fiber"; an embodiment that would be supported by Fig. 4A. In light of the above reasons, it is suggested that the recitation "first optical fiber" in Claim 12 be changed to "second optical fiber."

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-6, 8-9, and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view Polanyl (US 3,674,013).

In regard to Claim 1, Johnson discloses an implantable surgical drain 1 comprising an elongated conduit 2 configured to be implanted in and to drain from a body cavity (column 1, lines 7-10; column 2, lines 12-28). The drain 1 further comprises a first optical fiber 11, 21, 27 and a second optical fiber 11, 21, 27; the fibers are configured to transmit and receive energy from body tissue (column 1, lines 20-25 and lines 44-49; column 2, lines 12-22 and lines 51-66). Johnson discloses multiple optical fibers, any of which may be considered a first optical fiber and a second optical fiber. Johnson does not expressly disclose that the first distal end of the first optical fiber branches from the conduit. Polanyl teaches a fiber optic catheter with light emitting and light receiving optical fibers. Polanyl further teaches that the fibers are directed at an angle to one side of the catheter wall so that the optical fiber remains spaces from the body organs; and, as a result, this reduces the chance of unreliable or false readings from the body organ or cavity. One of ordinary skill in the art would have been motivated to branch the distal end of the first optical fiber from the conduit since having the fiber bend away from

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(branch from) the conduit allows the fiber to remain spaced from the body organ, thereby reducing the likelihood of inaccurate readings from the body cavity and organs. Thus, it would have been obvious to one of ordinary skill in the art to modify to branch the distal end of the first optical fiber of Johnson from the conduit since having the fiber bend away from (branch from) the conduit allows the fiber to remain spaced from the body organ, thereby reducing the likelihood of inaccurate readings from the body cavity and organs, as taught by Polanyl.

In regard to Claim 2, Johnson discloses that the optical fibers extend substantially parallel to each other; thus the distal ends of the optical fibers are substantially parallel to each other (Figs. 2-3 and 6).

In regard to Claim 3, Johnson discloses that the distal ends of the optical fibers are configured for insertion into tissue (column 2, lines 29-50).

In regard to Claim 4, Polanyl discloses a housing (collar 8) extending (inwardly) from the conduit supporting the fibers for insertion into a body (column 2, lines 17-23; Fig. 3).

In regard to Claims 5-6, Johnson discloses that the drain comprises a sensing system that can sense physiological properties, including oxygenation and pressure (column 1, lines 44-49; column 2, lines 16-22 and 33-36).

In regard to Claim 8, the fibers are embedded within the conduit (Johnson, Figs., column 3, lines 6-9).

In regard to Claim 9, Johnson discloses that the drain further comprises an oximeter that receives energy from the optical fibers 11, 21, 27 (column 2, line 62-column 3, line 5). The oximeter provides measurements, so it would have to display these

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measurements in some form to the user. Thus, the oximeter is considered analogous to a display.

In regard to Claim 12, the optical fiber 11, 21, 27 includes a component (such as surface or a distal end or any other portion of the fiber itself) affixed to the conduit 2 (Figs. 2-6; column 3, lines 6-9).

In regard to Claim 13, as discussed for Claim 8, Johnson discloses that the optical fiber 11, 21, 27, and therefore a component of the fiber, is embedded in the conduit (column 3, lines 6-9). Also see discussion for Claim 12.

In regard to Claim 14, as discussed for Claims 5-6, Johnson discloses that the component 11, 21, 27 can sense physiological properties, such as oxygenation; therefore the component 11, 21, 27 comprises a sensor (column 1, lines 44-49; column 2, lines 16-22 and 33-36).

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson in view of Polanyi as applied to claims 1-6 and 8-14 above, and further in view of Russo et al. (US 4,317,452).

In regard to Claim 7, as discussed previously, Johnson et al. in view of Polanyi disclose the claimed invention but do not expressly disclose that the conduit comprises a plurality of holes spaced along substantially the entire length of the drain portion. Russo et al. discloses a surgical drain comprising a conduit 10 having a plurality of holes along substantially the entire length of the drain portion (Fig. 1; column 2, lines 7-19; column 4, line 56-column 5, line). Russo et al. teach that having holes along a substantial

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portion of the conduit 10 allows body fluids in the cavity to pass into and along the conduit into a drainage site. One of ordinary skill in the art would have been motivated to provide Johnson in view of Polanyl with a plurality of holes in the tube wall to affect the manner in which fluid passes/flows into the tube. Thus, it would have been obvious to one of ordinary skill in the to provide the surgical drain of Johnson in view of Polanyl with a plurality of holes, as taught by Russo et al., since doing so would allow for body fluid to be drained from a body cavity along a substantial length of the tube and/or from a substantial portion of the body cavity.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Halili et al. (US 5,586,553) and Mann et al. (US 6,809,653).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keshia Gibson whose telephone number is (571) 272-7136. The examiner can normally be reached on M-F 8:30 a.m. - 6 p.m., out every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Keshia Gibson
Examiner
Art Unit 3761

klg 7/14/06

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

